



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of

Date: January 19, 2007

Keith K. Daellenbach

Our File No.: BJT 332B

Serial No. : 10/642.348

Examiner: Laura C. Schell

Filed : August 15, 2003

Group Art Unit: 3767

## END EFFECTOR FOR NEEDLE-FREE INJECTION SYSTEM

Mail Stop AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

**DECLARATION OF KEITH K. DAELLENBACH UNDER 37 C.F.R. 1.132**

I, Keith K. Daellenbach, declare:

1. I am the inventor named on U.S. Patent Application Serial No. 10/642,348.
  2. I am Director of Engineering Research at BIOJECT INC.
  3. I have a Bachelor of Science in Mechanical Engineering from Oregon State University (Corvallis, Oregon) and a Master of Science in Mechanical Engineering from Rensselaer Polytechnic Institute (Troy, New York).

4. I am a licensed professional mechanical engineer in the State of Oregon, and I have worked in the medical technology field for 11 years, and specifically in the area of needle-free injection systems for seven years.

5. My work has included the design, development, testing and commercialization of a number of needle-free injection systems that employ pressurized

gas as a source of pneumatic energy for injecting medical injectate into a human patient.

6. The attached graphs and figures contained in Exhibits A-C show the collected data and experimental setup for several tests performed to determine the upper-end pressures achievable with standard hypodermic syringes that were hand actuated. The tests were performed with the hypodermic syringes dead-headed to a pressure transducer.

7. To the best of my knowledge and analysis, dead-heading the hypodermic syringe provides a substantially accurate determination of the upper-end pressure that could be achieved by a standard hypodermic syringe that was hand actuated with typical human hand strength.

8. Exhibit A shows the results of a test performed with a 3 mL hypodermic syringe. The maximum pressure obtained with a dead-headed 3mL syringe was 229 psig.

9. Exhibit B shows the results of a test performed with a 5 mL hypodermic syringe. The maximum pressure obtained with a dead-headed 5mL syringe was 132 psig.

10. Exhibit C shows the results of a test performed with a 10 mL hypodermic syringe. The maximum pressure obtained with a dead-headed 10 mL syringe was 98 psig.

11. To the best of my knowledge and analysis, these test results show that standard hand-actuated hypodermic syringes, such as the one illustrated at reference number 86 in Figs. 4, 5, 9 and 10 of U.S. Pat. No. 6,905,475 to Hauschild et al., are only

capable of generating pressures that are significantly lower than the lower end of the needle-free pressure range of 643 psig to 2001 psig recited in U.S. Patent Application Serial No. 10/642,348.

12. I declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code. I understand that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 19 January 2007

  
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Keith K. Daellenbach